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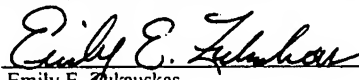
DOCKET NO.: C1037.70045US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Krieg et al.
Serial No.: 10/613,228
Confirmation No.: 4680
Filed: July 3, 2003
For: NUCLEIC ACID COMPOSITIONS FOR STIMULATING IMMUNE RESPONSES
Examiner: Nita M. Minnifield
Art Unit: 1645

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 6th day of December, 2006.


Emily E. Zukauskas

MAIL STOP AMENDMENT

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check in the amount of \$180 is enclosed to cover the filing fee. If the fee is insufficient, the balance may be charged to Deposit Account 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,

By:



Maria A. Trevisan, Reg. No.: 48,207
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
Telephone: (617) 646-8000

Docket No.: C1037.70045US00
Date: December 6, 2006
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Emily E. Zukauskas

MAIL STOP AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed more than three months after the filing date of this application and after the mailing date of the first Office action, but before the mailing date of any final action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in this application.

The fee of \$180.00 as set forth in 37 C.F.R. §1.17(p) is enclosed.

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PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified PTO/SB/08). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

| <u>Serial No.</u> | <u>Filing Date</u> | <u>Inventor(s)</u> | <u>Docket No.</u> |
|-------------------|--------------------|--------------------|-------------------|
| 11/595,823 | 11-10-2006 | Wagner et al. | *C1041.70035US01 |
| 11/598,207 | 11-10-2006 | Krieg et al. | *C1039.70048US24 |

*A copy of this reference is not provided as the Office has waived the requirement under 37 C.F.R. 1.98(a)(2)(iii) for submitting a copy of a cited U.S. patent application if it is scanned to the Image File Wrapper system and is available on Private PAIR.

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 (modified PTO/SB/08) be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

Serial No.: 10/613,228
Conf. No.: 4680

- 3 -

Art Unit: 1645

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his or her own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

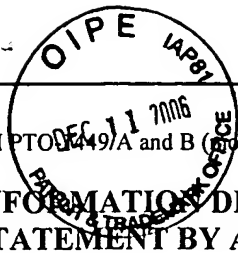
Respectfully submitted,

By:



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Date: December 6, 2006
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|  FORM PTO/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | APPLICATION NO.: 10/613,228 | ATTY. DOCKET NO.: C1037.70045US00 |
| | | FILING DATE: July 3, 2003 | CONFIRMATION NO.: 4680 |
| | | APPLICANT: Krieg et al. | |
| | | GROUP ART UNIT: 1645 | EXAMINER: Nita M. Minnifield |
| Sheet 1 of 2 | | | |

U.S. PATENT DOCUMENTS

| Examiner's Initials # | Cite No. | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication or Issue of Cited Document MM-DD-YYYY |
|-----------------------|----------|----------------------|-----------|---|---|
| | | Number | Kind Code | | |
| | A139 | 2004-0053880 | A1 | Krieg | 03-18-2004 |
| | A140 | 2004-0076905 | A1 | Yagihashi et al. | 04-22-2004 |
| | A141 | 2004-0234960 | A1 | Olek et al. | 11-25-2004 |
| | A142 | 2005-0019340 | A1 | Garcon et al. | 01-27-2005 |
| | A143 | 2005-0038239 | A1 | Catchpole | 02-17-2005 |
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FOREIGN PATENT DOCUMENTS

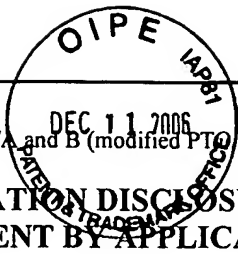
| Examiner's Initials # | Cite No. | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Translation (Y/N) |
|-----------------------|----------|-------------------------|----------|-----------|---|--|-------------------|
| | | Office/Country | Number | Kind Code | | | |
| | B23 | WO | 01/22972 | A2 | Coley Pharmaceuticals, GmbH | 04-05-2001 | |
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OTHER ART — NON PATENT LITERATURE DOCUMENTS

| Examiner's Initials # | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | Translation (Y/N) |
|-----------------------|---------|---|-------------------|
| | C59 | AGRAWAL et al., Medicinal chemistry and therapeutic potential of CpG DNA. Trends Mol Med. 2002 Mar;8(3):114-21. | |
| | C60 | BALLAS et al., Divergent therapeutic and immunologic effects of oligodeoxynucleotides with distinct CpG motifs. J Immunol. 2001 Nov 1;167(9):4878-86. | |
| | C61 | BITTON et al., Cancer vaccines: a critical review on clinical impact. Curr Opin Mol Ther. 2004 Feb;6(1):17-26. Abstract Only. | |
| | C62 | CHAN et al., CpG-A and CpG-B oligodeoxynucleotides differentially affect the cytokine profile, chemokine receptor expression and T-cell priming function of human plasmacytoid dendritic cells. Blood. 2002;100:50b. Abstract #3666. | |
| | C63 | DAVILA et al., Repeated administration of cytosine-phosphorothiolated guanine-containing oligonucleotides together with peptide/protein immunization results in enhanced CTL responses with anti-tumor activity. J Immunol. 2000 Jul 1;165(1):539-47. | |

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| EXAMINER: | DATE CONSIDERED: |
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



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|---|---|-----------------------------|-----------------------------------|
| FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | APPLICATION NO.: 10/613,228 | ATTY. DOCKET NO.: C1037.70045US00 |
| | | FILING DATE: July 3, 2003 | CONFIRMATION NO.: 4680 |
| | | APPLICANT: Krieg et al. | |
| | | GROUP ART UNIT: 1645 | EXAMINER: Nita M. Minnifield |
| Sheet | 2 | of | 2 |

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| C64 | DE GRUJIL et al., Cancer vaccine strategies get bigger and better. Nat Med. 1999 Oct;5(10):1124-5. | |
| C65 | DONNELLY et al., Cancer vaccine targets leukemia. Nat Med. 2003 Nov;9(11):1354-6. | |
| C66 | JAIN et al., Barriers to drug delivery in solid tumors. Scientific American. 1994; 271:58-65. | |
| C67 | KRIEG et al., Mechanisms and therapeutic applications of immune stimulatory CpG DNA. Pharmacol Ther. 1999 Nov;84(2):113-20. | |
| C68 | KRIEG et al., The CpG motif: Implications for clinical immunology. BioDrugs. 1998 Nov 1;10(5):341-6. | |
| C69 | LIANG et al., Activation of human B cells by phosphorothioate oligodeoxynucleotides. J Clin Invest. 1996 Sep 1;98(5):1119-29. | |
| C70 | LIPFORD et al., CpG-containing synthetic oligonucleotides promote B and cytotoxic T cell responses to protein antigen: a new class of vaccine adjuvants. Eur J Immunol. 1997 Sep;27(9):2340-4. | |
| C71 | MacFARLANE et al., Unmethylated CpG-containing oligodeoxynucleotides inhibit apoptosis in WEHI 231 B lymphocytes induced by several agents: evidence for blockade of apoptosis at a distal signalling step. Immunology. 1997 Aug;91(4):586-93. | |
| C72 | ROCHLITZ et al., Gene therapy of cancer. Swiss Med Wkly. 2001 Jan 12;131(1-2):4-9. | |
| C73 | VERMA et al., Gene therapy—promises, problems, and prospects. Nature. 1997 Sep18;389:239-42. | |
| C74 | VILE et al., Cancer gene therapy: hard lessons and new courses. Gene Ther. 2000 Jan;7(1):2-8. | |
| C75 | WEINER et al., The immunobiology and clinical potential of immunostimulatory CpG oligodeoxynucleotides. J Leukoc Biol. 2000 Oct;68(4):455-63. | |

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. __, filed __, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE – No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR §1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR §1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR §1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. §120.]

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